



## Vaxil BioTherapeutics announces positive interim results from its Phase I/II therapeutic cancer vaccine trial in Multiple Myeloma patients

The interim results were reported in regulatory filings made in connection with Vaxil's merger with Sheldonco Ltd. a 'shell company" traded on the Tel Aviv Stock Exchange

Nes-Ziona, Israel – April 2nd, 2012 – Vaxil BioTherapeutics, a clinical stage biotechnology company developing therapeutic vaccines for the treatment of cancer and infectious diseases, is merging with Sheldonco Ltd (TASE: SLDC), a "shell" company traded on the Tel Aviv Stock Exchange. The agreement was signed in February and is expected to complete in the coming months subject to various closing conditions set out in the regulatory filings (see link in Hebrew). <a href="http://maya.tase.co.il/bursa/report.asp?report\_cd=726136&CompCd=574">http://maya.tase.co.il/bursa/report.asp?report\_cd=726136&CompCd=574</a>.

Vaxil is developing ImMucin, a therapeutic vaccine to treat cancer, which was identified using the company's proprietary technology, VaxHit. ImMucin is a peptide vaccine derived from a unique sequence contained in the MUC1 tumor associated antigen which is present in 90% of all tumors. ImMucin educates the patient's immune system to identify and destroy cancer cells where the MUC1 marker is present.

Vaxil is currently evaluating ImMucin in a Phase I/II clinical trial in Hadassah Medical Center, Jerusalem in patients with Multiple Myeloma (a hematological cancer). A condition for enrollment in the study is that patients should be experiencing a gradual re-emergence of disease after a period of remission. Up to fifteen patients will be enrolled in the study; to date ten have been treated. The results of the interim report which are reported in the recent regulatory filings, relate only to seven patients who had finished the treatment with ImMucin.

The interim results demonstrate that ImMucin has a very high safety profile. No side effects were observed with the exception of minor local irritation which all resolved themselves within 24 hours without the need for any additional treatment or medical intervention. In addition, ImMucin generated a robust and specific immune response (of CD4+ and CD8+ T cells) in all patients which was observed after only 2-4 doses of the vaccine our of a maximum of 12 doses.

In some of the patients, preliminary signs of clinical efficacy were observed, including the stabilization or decrease of the disease markers, and a decrease in overall disease load as measured by the percentage of plasma cells in the patient's bone marrow, one month following the end of treatment as compared with prior to commencement of treatment. Of



the patients analyzed in the interim report, three are in complete response following ImMucin treatment.

Details of the merger agreement with Sheldonco were also released in the regulatory filing. According to the agreement, Vaxil will be acquired in its entirety by Sheldonco. The shareholders/option holders of Vaxil will receive 56% of the share capital of Sheldonco (on a fully diluted basis) and their holding will increase to 74% in Sheldonco (on a fully diluted basis) subject to achieving various milestones.

## **About Vaxil**

Vaxil was founded by Dr. Lior Carmon a biotechnology entrepreneur and expert in Immunology and cancer immunotherapy. Dr Carmon has a PhD in Immunology from the Weizmann Institute. Dr. Carmon was joined by Julian Levy who has worked with Lior Carmon for over a decade in various biotechnology ventures. Vaxil is developing therapeutic vaccines to treat cancer and a range of infectious diseases by generating an immune response.

As opposed to traditional prophylactic vaccines which protect healthy people from disease, a therapeutic vaccine deals with sick people and seeks to harness their immune system to identify and destroy cancer cells in a safe, efficient and focused manner. From the patient's perspective a therapeutic vaccine is a drug. ImMucin which was identified using Vaxil's proprietary technology, VaxHit, teaches the patient's immune system to identify and destroy cells which display the cancer marker MUC1 which appears on over 90% of all cancers. Consequently, ImMucin has the potential to be used against a wide range of cancers. In addition, ImMucin has a number of specific characteristics which differentiate it from other therapeutic vaccines. Firstly, ImMucin can be offered to a very wide section of the population with no need for complicated and expensive personalization or prior selection based on the patient's immune system. Second, ImMucin has the ability that may enable it to cope with the tendency of the tumor to evade the immune response and develop resistance to treatment.

In addition to ImMucin, Vaxil is also developing the MTbuVax therapeutic vaccine for TB with potential for prophylactic use. MTbuVax, which was also identified using VaxHit, is currently being evaluated in animal studies. Globally, TB is one of the largest causes of mortality. According to the WHO, in 2009, 9 million people worldwide were diagnosed as carrying the TB bacteria and 2 million died of it. Although most TB cases are in developing countries, over the last few years, there has been an increase in incidence rates in the western world due to the low efficiency of the current TB vaccine (BCG), increased global travel movements, the mutation of the TB bacteria to new strains which are partially or sometimes even totally resistant to drug treatment and the strong link of TB with HIV infection.

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